

**Remarks**

Applicants thank the Examiner for the very thorough consideration given the present application.

This Substitute Amendment is presented in reply to (1) the outstanding final office Action dated April 5, 2007, (2) the Advisory Action dated July 12, 2007, and (3) the Notice of Non-Compliant Amendment attached to the Advisory Action.

Claims 84-97 and 99-122 are now present in this application. Claims 84, 86, 103, 105, 109, 112, 114-115, and 119-121 are independent. By this Amendment, claims 87, 89, 90, 96, 105, 106, 110, 116 and 122 are amended, and claim 98 is canceled without prejudice, e.g., without prejudice to presenting it in a continuing application. No new matter is involved.

Reconsideration of this application, as amended, is respectfully requested.

**Entry of Amendments**

Applicants respectfully submit that it is proper to enter this Substitute Amendment, which cancels claim 98 and amends claims 96, 106, 110, 116 and 122 to permit entry of the Amendment and reduce and simplify the issues on appeal. The amendment also revises the remarks to be consistent with the aforementioned amendments.

**Rejection Under 35 U.S.C. § 112, 1st Paragraph**

Claims 96, 106, 110, 116 and 122 stand rejected under 35 U.S.C. § 112, 1st Paragraph for failing to comply with the written description requirement. This rejection is respectfully traversed.

The rejection is based on the premise that these five claims recite “the bypass protein level of the end product that is over 50% and up to about 83% of the crude protein is increased,” whereas there is no support in the specification, as originally filed, for the increase of the nutritional components of the end product, as recited in the claims.

Applicants respectfully disagree with this rejection regarding claims 96 and 110 because, those claims do not include the language “the bypass protein level of the end product that is over 50% and up to about 83% of the crude protein is increased.”

However, Applicants agree that claims 106, 116 and 122 do recite that the bypass protein level of the end product that is over 50% and up to about 83% of the crude protein is increased, and claims 106, 116 and 122 are amended to remove that language and, thereby overcome this rejection.

Additionally, solely to reduce and simplify the issues on appeal, Applicants are also amending claims 96 and 110 to delete the language “the bypass protein level of the end product that is over 50% and up to about 83% of the crude protein is increased.”

Accordingly, reconsideration and withdrawal of this rejection are respectfully requested.

*Rejection Under 35 U.S.C. § 112, 2<sup>nd</sup> Paragraph*

Claims 84-122 are rejected under 35 USC §112, second paragraph for reciting a relative term. This rejection is respectfully traversed.

The Office Action indicates that the term “an empirical relationship” in claims 84, 86, 103, 105, 109, 112, 114, 115 and 119-121 is a relative term that renders the claims indefinite. The Office Action further asserts that (1) this terminology is not defined by the claim; (2) the

specification does not provide a standard for ascertaining the requisite degree; and (3) one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Applicants respectfully disagree for the following reasons.

Firstly, Applicants have amended these claims to positively recite a combination of features including adjusting the temperature and/or the moisture content of the enhanced nutrient value by-product-nutrient source mixture based on an empirically derived relationship that relates the UIP as a percent of the crude protein (CP) to an end product temperature in a predictable and repeatable manner to produce said end product. Support for this language is found in Applicants' originally filed Application including, for example, in paragraph {0072} of Applicants' published Application, which states that regression analysis of the RUP/UIP of the nine batches heated and dried according to the methods described above yielded the following results. The R square value of the nutrient values of the nine batches indicates that 85.68% of the variation in UIP is the result of the end temperature of the mixture. This results in a calculated significance level of 0.0343% which means that 99.97% of the time, this RUP/UIP increase will occur. In other words, these results are highly predictable and repeatable.

In view of this, Applicants respectfully submit that Applicants have full support in their Application, as filed, for the language in issue, that the language in issue has a clear and definite meaning to one of ordinary skill in the art, and that the claim language of adjusting the temperature and/or the moisture content of the enhanced nutrient value by-product-nutrient source mixture based on an empirically derived relationship that relates the UIP as a percent of the crude protein (CP) to an end product temperature in a predictable and repeatable manner to

produce said end product, is actually based on objective factual evidence that 99.97% of the time, this RUP/UIP increase will occur.

Furthermore, one of ordinary skill in the art only has to follow Applicants' detailed disclosure, which includes numerous examples, to empirically derive relationship that relates the UIP as a percent of the crude protein (CP) to an end product temperature in a predictable and repeatable manner to produce end products for other starting materials than those explicitly disclosed.

Moreover, Applicants respectfully submit that an empirically derived relationship is conventionally defined as a relationship that is derived from, and is based upon, controlled experiments. A careful reading of Applicants' disclosure reveals that they disclose a number of controlled experiments which support an empirically derived formula recited in the claims.

Additionally, Applicants provide the following definitions of a formula from well known, encyclopedic sources, readily available on the Internet, that clearly demonstrate that the empirical formula recited in the claims is an empirical relationship.

1. The Columbia Electronic Encyclopedia defines a formula, in mathematics and physics, as an equation expressing a definite fixed relationship between certain quantities. The quantities are usually expressed by letters, and their relationship is indicated by algebraic symbols. For example,  $A=\pi r^2$  is the formula for the area  $A$  of a circle of radius  $r$ , and  $s=1/2at^2$  is the formula for the distance  $s$  traveled by a body experiencing an acceleration  $a$  during a time interval  $t$ . The effective date of this reference is 2004.

2. Wikipedia, the free encyclopedia, defines formula, in mathematics and in the sciences, as a concise way of expressing information symbolically (as in a mathematical or chemical formula), or a general relationship between quantities. One of many famous formulae is Albert Einstein's  $E=mc^2$  (see special relativity).

Accordingly, Applicants respectfully submit that the terminology “an empirical relationship” has a well known meaning and that its metes and bounds are readily able to be determined by one of ordinary skill in the art.

Thus, claims 84, 86, 103, 105, 109, 112, 114, 115 and 119-121 fully comply with the requirements of 35 USC §112, second paragraph.

Accordingly, reconsideration and withdrawal of this rejection are respectfully requested.

Claim 98 is rejected because it lacks proper antecedent basis for the language “air temperature of the dryer.” Moreover, the Advisory Action indicates that the after-final amendment to this claim would require further consideration and/or search and, for this reason, the after-final amendment would not be entered. This rejection is respectfully traversed as moot because Applicants have, by this Substitute Amendment, canceled claim 98 without prejudice to presenting it in a continuing application.

Reconsideration and withdrawal of this rejection of claim 98 are respectfully requested.

Claims 87, 89, 90, 96, 106, 110, 116 and 122 recite the terminology “wet byproducts soluble nutrient source mixture” and “wet soluble nutrient source mixture”, which does not find proper antecedent basis in the claim(s) from which these claims depend. This rejection is respectfully traversed. Applicants respectfully submit that the quoted terminology is not found in claims 96, 106 and 110. However, claims 87, 89, 90, 116 and 122 have been amended to obviate this issue by substituting terminology that finds proper antecedent basis in the claim(s) from which these amended claims depend.

Accordingly, reconsideration and withdrawal of this rejection of claims 86, 89, 90, 96, 106, 110, 116 and 122 are respectfully requested.

Claims 87, 89, 90, 96, 106, 110, 116 and 122 stand rejected under 35 USC §112, second paragraph as being incomplete for omitting essential elements, such omission amounting to a gap between the elements, citing MPEP §2172.01. This rejection is respectfully traversed.

The Office Action asserts that the claims refer to increasing the nutrient values of a source mixture but do not refer to the method by which this is done and, because of this, it is unclear in which step of the independent claim an increased nutrient value is achieved. For example, the Office Action indicates that it is unclear in claim 87 if the nutrient value increase is increased in step a of claim 84, step b of claim 84, or in some other undisclosed step.

Applicants respectfully submit that the rationale stated to support this rejection does not support the rejection. In other words, the Office Action does not explain what a failure to understand exactly where, in the overall claimed process, an increased nutrient value is achieved, has to do with the claims omitting essential elements. Nor does the Office Action explain what a failure to understand exactly where, in the overall claimed process, an increased nutrient value is achieved has to do with the claims omitting essential elements. Moreover, for reasons discussed below, Applicants respectfully submit that these issues do not impact on the issue of whether Applicants' claims comply with the requirements of 35 USC §112, second paragraph.

What is in issue in a rejection under 35 USC §112, second paragraph has been explained by the Court of Appeals for the Federal Circuit and only the test that the court provides for compliance with the second paragraph needs to be met by the claims. The test for compliance

with the second paragraph of 35 U.S.C. §112, as stated in Miles Lab., Inc. v. Shandon Inc., 997 F.2d 870, 875, 27 USPQ2d 1123, 1126 (Fed. Cir. 1993), cert. denied, 510 U.S. 1100 (1994) is whether one skilled in the art would understand the bounds of the claims when read in light of the specification. If the claims, read in light of the specification, reasonably apprise those skilled in the art of the scope of the invention, Section 112 demands no more. See, also, In re Merai, 519 F.2d 1390, 1396, 186 USPQ 471, 476 (CCPA 1975), which stated that the question under Section 112, second paragraph is whether the claim language, when read by a person of ordinary skill in the art in light of the specification, describes the subject matter with sufficient precision that the bounds of the claimed subject matter are distinct. See, also, In re Warmerdam, 33 F3d 1354, 1361, 31 USPQ2d 1754, 1759 (Fed. Cir. 1994). Moreover, this claims recites "substantially." Use of that term in a claim does not render the claim indefinite if the specification provides a standard whereby one of ordinary skill in the art would understand what is claimed when the claim is read in light of the specification, Seattle Box Co., Inc. v. Industrial Coating and packing, Inc., 731 F.2d 818, 826, 221 USPQ 568, 573-4 (Fed. Cir. 1984).

The second paragraph of 35 U.S.C. §112 requires claims to be set out and circumscribe a particular area with a reasonable degree of precision and particularity. In re Johnson, 558 F.2d 1008, 1015, 194 USPQ 187, 193 (CCPA 1977).

Applicants respectfully submit that the claims fully comply with 35 U.S.C. §112, second paragraph as they stand because one of ordinary skill in the art can readily determine the metes and bounds of the invention to determine whether or not they infringe the claimed invention and can do so without speculating as to exactly where, in the claimed process, an increased nutrient value is achieved.

Moreover, the case cited in MPEP §2172.01 (on which this rejection is based) to require inclusion of essential structural cooperative relationships, In re Mayhew, 188 USPQ 356 (CCPA 1976), involved method claims that omitted a step without which the invention as claimed was wholly inoperative (meaning it simply would not work and could not produce the claimed product). That is not the situation here.

Furthermore, the Office Action is not applying "In re Mayhew" in the context in which it was presented, i.e., for omitting an essential element that was required to make the method claims operative but, instead, as a license to require that Applicant redefine his invention the way the Examiner wants it to be defined, instead of the way every applicant is entitled to define it.

The Court of Customs and Patent Appeals has addressed this issue and resolved it long ago in In re Borkowski, 164 USPQ 642, 645 (CCPA 1970), where the court stated that "[W]hile the examiner states the requirement to be claims which "particularly point out and distinctly claim *the invention*" (emphasis added), § 112 actually requires claims "particularly pointing out and distinctly claiming *the subject matter which applicant regards as his invention*" (emphasis added). In reality, this means that applicant must particularly point out and distinctly claim the "*subject matter sought to be patented*".

In other words, as explained in the "Borkowski" decision, an Applicant is free to define what he or she regards as the invention, and it is improper for an Examiner to tell the Applicant how to claim what the Applicant regards as his invention as long as the metes and bounds of the invention are clear and definite, as they are in the claims under rejection. Moreover, it is noted that the Examiner fails to indicate that the metes and bounds of the claim are unclear.

Accordingly, the rejection of claims 87, 89, 90, 96, 106, 110, 116 and 122 is improper



and should be withdrawn.

Claims 109-111 and 119-122 stand rejected under 35 USC §112, second paragraph as being indefinite. This rejection is respectfully traversed.

These claims are allegedly indefinite because it is unclear what apparatus is associated with the system, e.g., what apparatus is necessary for “a system determining means for determining the desirable levels of crude protein in the feed composition.” The Office Action states that it is unclear if the system is based on personal observation of the animal for which the feed is to be fed, and if the system is based on chemical observation of the animal to which the feed is to be fed.

Applicants respectfully submit that this rejection is improper for a number of reasons.

Firstly, as explained above, Applicants do not understand why this rejection is based on the second paragraph of 35 USC §112, because, as pointed out above, the test for compliance with the second paragraph of 35 U.S.C. §112, as stated in Miles Lab., Inc. v. Shandon Inc., 997 F.2d 870, 875, 27 USPQ2d 1123, 1126 (Fed. Cir. 1993), cert. denied, 510 U.S. 1100 (1994) is whether one skilled in the art would understand the bounds of the claims when read in light of the specification. If the claims, read in light of the specification, reasonably apprise those skilled in the art of the scope of the invention, Section 112 demands no more. See, also, In re Merat, 519 F.2d 1390, 1396, 186 USPQ 471, 476 (CCPA 1975), which stated that the question under Section 112, second paragraph is whether the claim language, when read by a person of ordinary skill in the art in light of the specification, describes the subject matter with sufficient precision that the bounds of the claimed subject matter are distinct. See, also, In re Warner, 33 F3d

1354, 1361, 31 USPQ2d 1754, 1759 (Fed. Cir. 1994). Moreover, these claims recite "substantially." Use of that term in a claim does not render the claim indefinite if the specification provides a standard whereby one of ordinary skill in the art would understand what is claimed when the claim is read in light of the specification, Seattle Box Co., Inc. v. Industrial Coating and Packing, Inc., 731 F.2d 818, 826, 221 USPQ 568, 573-4 (Fed. Cir. 1984). Applicants respectfully submit that this terminology is clear to one of ordinary skill in the art based on Applicants' disclosure.

Moreover, the second paragraph of 35 U.S.C. §112 requires claims to be set out and circumscribe a particular area with a reasonable degree of precision and particularity, In re Johnson, 558 F.2d 1008, 1015, 194 USPQ 187, 193 (CCPA 1977).

Applicants respectfully submit that the claims fully comply with 35 U.S.C. §112, second paragraph as they stand and because one of ordinary skill in the art can readily determine the metes and bounds of the invention to determine whether or not they infringe the claimed invention.

With respect to the issue of whether one of ordinary skill in the art is capable of determining what type of apparatus can be used to determine desirable levels of crude protein in the feed composition, Applicants respectfully submit that one of ordinary skill in this art to which this invention pertains is capable of doing so. In this regard, Applicants respectfully submit that the burden of establishing a *prima facie* case to support this rejection, is on the Office, not on the Applicants and the Office Action fails to even address the level of one of ordinary skill in this art, as is required to make a rejection of this type, which appears to be more

related to sufficiency of disclosure that the issues covered by the second paragraph of 35 USC §112.

Applicants respectfully submit that factors to be considered by an Examiner in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of guidance or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. See In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988), citing Ex parte Formal, 230 USPQ 546, 547 (Bd. Pat. App. & Int. 1986).

Unfortunately, the outstanding Office Action fails to address these eight factors at all, let alone with the required objective factual evidence in support thereof, and for the reasons presented above and for these additional reasons, the Office Action fails to make out a *prima facie* case of failure to comply with 35 USC §112, second paragraph.

Accordingly, reconsideration and withdrawal of this rejection of claims 109-111 and 119-122 are respectfully requested.

### Rejections Under 35 U.S.C. § 103

Claims 84-122 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent 5,824,355 to Hietritter et al. ("Hietritter") in view of U.S. Patent 5,219,596 to Schingoethe (Feed Wet Distillers Grains to Dairy Cattle, May 2001). This rejection is respectfully traversed.

In rejecting claims under 35 U.S.C. § 103, it is incumbent on the Examiner to establish a factual basis to support the legal conclusion of obviousness. See, In re Fine, 837 F.2d 1071,

1073, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988). In so doing, the Examiner is expected to make the factual determinations set forth in Graham v. John Deere Co., 383 U.S. 1, 17, 148 USPQ 459, 467 (1966), and to provide a reason why one of ordinary skill in the pertinent art would have been led to modify the prior art or to combine prior art references to arrive at the claimed invention. Such reason must stem from some teaching, suggestion or implication in the prior art as a whole or knowledge generally available to one having ordinary skill in the art. Uniroyal Inc. v. F-Wiley Corp., 837 F.2d 1044, 1051, 5 USPQ2d 1434, 1438 (Fed. Cir. 1988), cert. denied, 488 U.S. 825 (1988); Ashland Oil, Inc. v. Delta Resins & Refractories, Inc., 776 F.2d 281, 293, 227 USPQ 657, 664 (Fed. Cir. 1985), cert. denied, 475 U.S. 1017 (1986); ACS Hospital Systems, Inc. v. Montefiore Hospital, 732 F.2d 1572, 1577, 221 USPQ 929, 933 (Fed. Cir. 1984). These showings by the Examiner are an essential part of complying with the burden of presenting a *prima facie* case of obviousness. Note, In re Oetiker, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification. In re Fritch, 972 F.2d 1260, 1266, 23 USPQ2d 1780, 1783-84 (Fed. Cir. 1992). To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be suggested or taught by the prior art. In re Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1970). All words in a claim must be considered in judging the patentability of that claim against the prior art. In re Wilson, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970).

A showing of a suggestion, teaching, or motivation to combine the prior art references is an "essential evidentiary component of an obviousness holding." C.R. Bard, Inc. v. M3 Sys. Inc.,

157 F.3d 1340, 1352, 48 USPQ2d 1225, 1232 (Fed. Cir. 1998). This showing must be clear and particular, and broad conclusory statements about the teaching of multiple references, standing alone, are not “evidence.” See In re Dembiczak, 175 F.3d 994 at 1000, 50 USPQ2d 1614 at 1617 (Fed. Cir. 1999). Moreover, a factual inquiry whether there is proper motivation to modify a reference must be based on objective evidence of record, not merely conclusory statements of the Examiner. See, In re Lee, 277 F.3d 1338, 1343, 61 USPQ2d 1430, 1433 (Fed. Cir. 2002).

Moreover, it is well settled that a rejection based on 35 U.S.C. § 103 must rest on a factual basis, which the Patent and Trademark Office has the initial duty of supplying. In re GPAC, Inc., 57 F.3d 1573, 1582, 35 USPQ2d 1116, 1123 (Fed. Cir. 1995).

I. Initially, Applicants note neither of these two applied references discloses or suggests a number of positive features of the claims invention.

Hietritter neither discloses nor suggests a number of positively recited features of the claims for a number of reasons.

Firstly, Hietritter does not disclose or suggest a method for predictably enhancing the nutrient value of distillers, brewers or fermenting grain products, as recited in all pending claims. The rejection never mentions this positively recited “predictable” feature of the claimed invention, which it must do. In this regard, Applicants respectfully submit that, to establish *prima facie* obviousness of a claimed invention, all the claim limitations must be suggested or taught by the prior art. In re Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1970). All words in a claim must be considered in judging the patentability of that claim against the prior art. In re Wilson, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). In this regard, Hietritter discloses absolutely no concept of predictably enhancing the nutrient value of grain by-products.

Secondly, Hietritter does not (1) determine specific desirable nutrient values of an end product; and (2) creating a distillation and/or fermentation by-product-nutrient source mixture having an enhanced nutrient value by (a) adding one or more crude protein and/or amino acid content nutrient sources comprising canola meal, soybean meal, sunflower meal into wet distillers, brewers or fermenters byproducts based on the crude protein, UIP protein, amino acid content, UIP/RUP amino acid content of the added nutrient sources to create an enhanced nutrient value by-product-nutrient source mixture of the distillation or fermentation byproducts; and (b) adjusting the temperature and/or the moisture content of the enhanced nutrient value by-product-nutrient source mixture based on an empirical relationship that relates the UIP as a percent of the crude protein (CP) to an end product temperature to produce said end product with those specific desirable nutrient levels, as claimed. Hietritter does not disclose this combination of features. All that Hietritter performs is step (2), but not steps 2a, 2b or (3). In this regard, Hietritter merely mixes various ingredients, adds water, cooks them, comes up with end products, and measures certain nutrient values. That's it. Hietritter simply does not disclose or suggest performing steps (1), 2a, 2b and (3), which are a positively recited part of Applicants' unique processes.

Thirdly, with respect to claim 86, the Office Action does not even address this specific positively recited feature of adjusting UIP as a percent of the crude protein according to a specific recited formula which is nowhere to be found, either explicitly or inherently (i.e., necessarily disclosed) in Hietritter.

Fourthly, Schingoethe, the secondary reference in the applied reference combination, fails to disclose or suggest any of the features that are missing from Hietritter. Accordingly, no

matter how these references are combined, the resulting reference combination cannot possibly disclose these missing positively recited claimed features.

The Office Action fails to make out a *prima facie* case that Hietritter, the base reference used in the applied reference combination, discloses a number of positively recited features of the claimed invention.

Moreover, Applicants respectfully submit that following Heitritter's teachings will never result in the claimed invention in the sense that Heitritter never adds any nutrient values to his starting product to increase its nutrient value before heating it or adding water to it, as claimed. In this regard, the Office Action fails to provide objective factual evidence that one of ordinary skill in the art would be properly motivated to modify Heitritter to add any nutrients to his starting product to increase its nutrient value, especially where Heitritter's starting material already has reasonable levels of nutrient values.

Applicants respectfully submit that Applicants' claimed invention involves realizing something that none of the applied art realizes and recites a method that capitalizes on that something, i.e., an empirically derived formula that they realized can be used in the claimed method, whereas neither the knowledge of the existence of the empirical formula nor the claimed method never has existed, nor is in any way suggested by, the applied art.

The Office Action continues by admitting that Hietritter does not disclose (1) wet distillers, brewers or fermenters grain byproducts as a part of the product base, as recited in claims 84, 103, 105, 109, 112, 114, 115 and 119; (2) a specific ratio of wet distillers grain to soy meal as recited in claim 91; (3) the percentage of RUP that has increased, as recited in claims 87, 96, 106, 110, 116 and 122; (4) a drying temperature of 350-500 degrees Fahrenheit, as recited in

(now canceled) claim 98; and (5) and the parameters and equations as recited in claims 86, 89, 90, 94 and 95.

Actually, these are not all of Hietritter's shortcomings. Hietritter does not (1) predetermine nutrient values of the end product; (2) add any nutrient source that would affect the protein and/or amino acid levels; (3) predict end product UIP level according to temperature achieved during cooking and/or drying, whereas Applicants disclose adjusting the temperature and/or the moisture content of the enhanced nutrient value by-product-nutrient source mixture based on an empirical relationship that relates the UIP as a percent of the crude protein (CP) to an end product temperature to predictably achieve desired nutrient values, and even recite in claim 86, a specific empirically obtained formula to predict this:  $UIP(\% \text{ of CP}) = (\text{End product temperature } ^\circ\text{F} \times 0.819) - 107.644$ ; or (4) mention the use of any fermentation products, either wet or dry.

In a previous Office Action, in an attempt to remedy Hietritter's admitted deficiencies, the Office Action turned to Smith, which discloses that "by properly adjusting a particular feed composition to deliver essential amino acids in balance post-ruminally, overall production is enhanced and deficiencies and excesses are minimized" — see col. 2, lines 16-19 of Smith.

Despite the admitted shortcomings of Hietritter, the Office Action does not turn to a secondary reference to modify Hietritter as it turned to Smith to modify Hietritter in a previous Office Action. The secondary reference relied on in the outstanding rejection is not used to provide the teaching that Smith was used to supply. This is a tacit admission that the outstanding rejection based on Hietritter and the current secondary reference is inadequate. Turning to the newly applied secondary reference, i.e., Schingoethe, Applicants respectfully submit that



Schingoethe presents a review of known studies on feeding both wet and dry corn distillers grains. In all these studies using lactating dairy cows, a total ration has to be made so that all their nutrient requirements are satisfied. The corn distillers grains would have been mixed in with the minerals, vitamins, wet corn silage, wet hay/silage, dry hay, grain products (including ground corn, wheat middlings, etc.) and protein products according to the experimental protocol. This is all done at the farm level and there is no disclosure that further processing is, or can be, performed on any single ingredient at that time.

Moreover, Applicants submit that it would be deleterious to try to heat up this total mixed ration in the hopes of increasing the RUP because a cow needs only about 35% of her protein in the form of RUP and any increase in RUP beyond this is wasteful - plus it would take valuable RDP (rumen degradable protein) away from the cow.

Combining the teachings of Heitritter and Schingoethe leaves us with a total mixed ration for lactating dairy cows. Applicants respectfully submit that looking at the 40 to 50 ingredients going into this ration will properly motivate one of ordinary skill in the art to start mixing wet materials with dry ones and then heat treating until they are dry.

In this regard, Applicants respectfully point out that, as Schingoethe discloses, corn distillers grains have been available for as long as alcohol has been distilled. Over the past 1000 years or more, this material undoubtedly has been fed to livestock. Similarly, soybean production has been in practice for the past 100 years or more and its waste product (soybean meal) has also been fed to animals. With such a long history for each, the fact that no one has combined the two in the production of a novel ingredient indicates that it is not obvious for one trained in the art to do so.

The previous Office Action stated that, regarding an empirical formula as describing the method of enhancing the feed product taught by Heitritter, Heitritter teaches two specific points (the RUP/UIP levels and coordinating end product temperatures) which allegedly permits derivation of an empirical formula that relates UIP and the end product temperatures to alternatively explain the method of increasing the nutrient value in the fed product as taught by Heitritter.

Applicants previously replied by stating that they did not fully understand this rejection as it relates to disclosing the claimed feature of predictably enhancing the nutrient value of a feed product based on an empirical formula, and respectfully submit that Heitritter completely fails to disclose the claimed empirical formula for RUP production for the following reasons:

1) Heitritter gives data in only one of his examples, i.e., Table II, concerning temperature and RUP. In the explanation of the table he states that the cooked material had a temperature of 200°F and the table shows that this material reached a RUP of 69.6% of the crude protein as compared to only 25.6% RUP in the uncooked product. In order to draw a line between these two points so as to calculate the slope of the line we need to know the temperature of the uncooked product. We assume it was “ambient temperature,” but Heitritter does not explicitly state what it is. Further, in this regard, if the production was done in a heated building this temperature might be about 70 degrees F., and if the production was done in an unheated building (as is the norm in production) the temperature may be close to freezing as in the winter or above 85 degrees F., as in the Summer.

For statistical analysis of the data set one needs paired values, that is a series of RUP values for given cooked temperatures. As indicated above, the paired value for the first RUP

reported by Heitritter is not disclosed, and thus no statistical analysis of Heitritter's data is possible.

Contrarily, the Haschen-Patterson data has multiple paired measurements (see table 14). Regression analysis was computed on the various paired measurements given in this table using the statistical package found in Microsoft Excel. The results of this analysis for the independent variable of product temperature and the dependent variable of UIP/RUP is given in table 8, which is reproduced below for the Examiner's convenience.

The  $r^2$  value of 0.8568 means that 85.68% of the variation in the UIP/RUP value is determined by the temperature the product reached while cooking (end temperature). This is highly statistically significant as indicated by the F value and the significance is calculated as 0.000343, which means that 99.97% of the time this relationship will hold true. The analysis gives us the y intercept as -107.644 and the x variable as 0.8190. This means that the empirical formula for calculating the UIP/RUP is as follows:

$$\text{UIP}(\% \text{ of CP}) = (\text{EndTemp } ^\circ\text{F} \times 0.819) - 107.644$$

**Regression Analysis of Experimental Mixtures**

TABLE 8

**REGRESSION OF UIP % OF CP AND END TEMPERATURES**

**SUMMARY OUTPUT**

REGRESSION OF UIP % OF CP AND END TEMPERATURES					UIP CP			
SUMMARY OUTPUT								
			Std. Error	Average				
Regression Statistics								
Multiple R	0.9256539		195	53.68				
R Square	0.856944309		218	74.60				
Adjusted R Square	0.836399598		229	82.93				
Standard Error	3.338503243		208	65.87				
Observations	8		219	87.45				
ANOVA								
	df	SS	MS	F	Significance			
Regression	1	466.9707329	466.9707329	41.89704214	0.000542787			
Residual	7	78.91022732	11.408009					
Total	8	544.9559602						
	Coefficients	Standard Error	t Stat	P-value	Lower 95%	Upper 95%	Lower 95.0%	Upper 95.0%
Intercept	-107.8440602	20.91699989	-3.9991904	0.000195469	-171.2919273	-43.9862568	171.2919273	43.9962568
X Variable 1	0.818890743	0.126605442	6.47285425	0.000342787	0.910789829	1.118165659	0.918789829	1.118165659

Heitritter does not teach of the points of RUP/UIP levels and temperatures. Applicants respectfully submit that there is no way that such relationships can be extrapolated from Heitritter's disclosed data because Heitritter discloses only one value for his cooking temperature.

Additionally, Heitritter discloses that his product reaches a temperature of 200 degrees Fahrenheit and that this results in a RUP value of 69.9% of the crude protein. If one enters the 200 degrees Fahrenheit into Applicants' empirical formula, the result is an RUP value of 56.16%, and not the 69.9% that Heitritter discloses. Thus, Heitritter does not achieve, or anticipate, or suggest, or otherwise render obvious, the claimed invention.

Furthermore, Applicants respectfully submit that, while Heitritter demonstrates a method of creating a higher rumen bypass protein by cooking a mixture of oil seed meal mixed with hulls, Heitritter does not enhance the mixture he is creating to change any of the protein and/or amino acid levels appreciably and he never does it predictably nor does he provide one of

ordinary skill in the art the data that would permit them to do so, even with further invention. Heitritter simply cooks the product to increase the UIP/RUP. Heitritter's feeding of this product to lactating cows further demonstrates that the UIP was indeed increased as was measured when the sample of product was incubated in the rumen of a cow and measured for protein disappearance. This was the method that gave the value of 69.9% RUP as % of CP. Feeding to the lactating cows in the experiment did not yield a value for the RUP other than to indicate it had increased.

Applicants' claimed invention is completely different. Applicants' claimed process enhances corn distillers dried grains by changing the crude protein and amino acid levels so that it has more economic value by mixing the wet corn distillers grains with a nutrient source, e.g., soybean meal, at predetermined levels in order to achieve a variety of outcomes. This mixture is then heated to specific temperatures, based on an empirically derived relationship (formula), to achieve the desired levels of UIP/RUP. Use of this claimed method results in production of a multitude of feed products with predictably enhanced nutritional values that meet the needs of different users.

Furthermore, Heitritter does not predetermine the levels of crude protein and amino acids or the UIP/RUP that the end product will contain. He makes the product and then analyses to see what levels were achieved. For example, Heitritter's process does not vary to achieve a variety of possible outcomes.

In response to this argument, the Office Action states that Heitritter teaches increasing milk production in cattle as a direct result of feeding the cattle with nutrient enhanced feed and that the increased is a direct result of the disclosed method of enhancing the nutrient value of

feed to specific values that provide for the increased milk production, referencing Heitritter, col. 2, lines 50-60 and col. 9, lines 15-53.

Applicants respectfully submit that this characterization of Heitritter is not accurate. A review of Heitritter reveals that Heitritter completely fails to disclose any specific levels of crude protein and amino acids or the UIP/RUP that the end product will contain. Heitritter also fails to predetermine any specific levels of crude protein and amino acids or the UIP/RUP that the end product will contain. There is a good reason for this, which is that Heitritter does contain any clues, hints or suggestions that would trigger a sequential process that would result in, or otherwise render obvious, the claimed invention, and Heitritter does not have an empirically derived formula to use to achieve the predetermined levels in any manner whatsoever, let alone predictably, as claimed.

Additionally, the two references applied in this rejection teach away from being combined, as suggested. A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the Appellant. The degree of teaching away will of course depend on the particular facts; in general, a reference will teach away if it suggests that the line of development flowing from the reference's disclosure is unlikely to be productive of the result sought by the Appellant. See W.L. Gore & Assoc., Inc. v. Garlock, Inc., 721 F.2d 1540, 1550-51, 220 USPQ 303, 311 (Fed. Cir. 1983) (the totality of a reference's teachings must be considered), cert. denied, 469 U.S. 851 (1984); In re Sponnoble, 405 F.2d 578, 587, 160 USPQ 237, 244 (CCPA 1969) (references taken in combination teach away since they would produce a "seemingly inoperative device"); In re Caldwell, 319 F.2d 254,

256, 138 USPQ 243, 245 (CCPA 1963) (reference teaches away if it leaves the impression that the product would not have the property sought by the Appellant). See, In re Gurley, 31 USPQ2d 1130 (Fed. Cir. 1994).

In this regard, Heitritter's invention uses oil seed meals mixed with hulls (example soybean meal and soybean hulls). Heitritter's patent calls for the use of oil seed meals. Oil seeds are plants that are grown specifically for their high oil content, the most common in North America being soybeans (18% oil), canola (40% oil), sunflowers (25% oil) and flax (35% oil). There are a few other crops from which oil is extracted but as a secondary product and these include peanuts, cotton and corn. Corn has about 3.5% oil in the grain and corn oil is extracted only after the oil has been concentrated in some of the byproducts formed during the refining of corn starch. In Applicants opinion, corn is grown for its starch content and not its oil and is not considered an oil seed by one of ordinary skill in the art to which this invention pertains. Corn is also very low in crude protein being about 7 to 9% and thus does not suit this invention. Heitritter does not mention "corn" or "corn byproducts" in the patent because they are not suitable for his end product. Adding soybean hulls based on Schingoethe's generic historical disclosure would not enhance the nutrient source and, in fact, would reduce the nutrient levels because the hulls are very much inferior in nutrient levels compared to soybean meal. As example of this, consider that soybean meal is about 48% crude protein and soybean hulls are only about 10% crude protein. Mixing the two will result in a product that is below 48% crude protein. Therefore, one of ordinary skill in the art will not be properly motivated to modify Heitritter in view of Schingoethe, as suggested.

More importantly, even if it were obvious to modify Hietritter in view of Schingoethe, which it is not for reasons discussed above, Hietritter, as modified, would not disclose or render obvious the claimed invention because Hietritter lacks two of the three positively recited features in the independent claims under rejection.

III. The Office Action further asserts that it would be obvious to one of ordinary skill in the art to include an increase in the amount of RUP depending on the desired final product and the amount of RUP in the starting material (see page 6, last three lines). Unfortunately, absolutely no factual evidence, let alone any objective factual evidence, is presented to support this speculative conclusion. Moreover, as pointed out above, both applied references fail to contain a disclosure of several positively recited features, including the predictability feature and steps (1) and (3), as discussed above. In other words, this assertion attempts to make something out of nothing, i.e., lack of disclosure, but that is not logically possible. Accordingly, this assertion is improper and should be withdrawn.

IV. With respect to the UIP as a percentage of the crude protein that is recited in claims 86, 96, 106, 110, 116 and 112, the claimed percentages are simply not disclosed nor are they obvious. The only stated basis for rejecting these claims under 35 USC §103(a) rests on the "112 rejections above." That rejection indicated that it was unclear what RUP source feed is increased and what initial amount of RUP is increased. In this regard, Applicants respectfully submit that the initial RUP is what is in the created distillation and/or fermentation by-product-nutrient source mixture recited in those claims. The claimed percentages of the UIP as a percentage of the crude protein is simply not disclosed or suggested by Hietritter.



V. Furthermore, with respect to claim 86, this claim recites more than a specific range. Claim 86 positively recites that the UIP as a percent of the crude protein is adjusted according to a specific formula – which is nowhere disclosed or suggested by any of the applied art.

VI. Additionally, with respect to claims 86, 89, 90, 94 and 95, the Office Action says that because it is not equipped to manufacture the product, the burden shifts to Applicants to demonstrate that the prior art product used in rejecting the claimed invention is different. While Applicants disagree with this proposition that the burden shifts to Applicant because the Office does not have the wherewithal to test the products disclosed or suggested by the Hietritter/Schingoethe reference combination, no case law is presented to support this unique argument, which is contrary to all of the case law cited above. In fact, it is contrary to the established case law cited above, which requires that the office make out a *prima facie* case of unpatentability before the burden shifts to Applicants.

VII. Moreover, as noted above, claim 86 recites more than a specific range of values. Claim 86 positively recites that the UIP as a percentage of the crude protein is adjusted according to a particular empirically established formula determined by Applicants that is neither disclosed nor suggested by either of the applied references. In this regard, it is instructive to note that the claimed ranges in these claims under rejection are readily obtainable because of Applicants' invention and are not contemplated by either of the applied references, neither of which discloses any understanding of the claimed invention.

VIII. With respect to the claimed empirical formula, the outstanding Office Action states that different processes can be explained through different means, e.g., gravity can be

explained through the process of a pencil dropping or through a mathematical equation, and although different means may be used to explain a process, the process remains the same. It appears that the rationale being used here is that the applied art discloses or suggests the claimed empirical formula relating UIP to end product temperature. Applicants disagree with this conclusion for the numerous reasons set forth above. Applicants also respectfully submit that the claimed invention is not an empirical formula, *per se*, but recites a practical application of the empirical formula to achieve a useful, concrete and tangible result, which was never contemplated by either applied reference, alone or in combination. Moreover, the conclusion that all that Applicants are claiming is "heating a feed composition to a temperature of at least 200 degrees F, and producing the same product, i.e., a feed composition with an RUP level of 69.9%" reads out of the claims, several positively recited features of those claims, and is improper for this reason, as well.

IX. A fair balanced review of the applied art reveals that neither applied reference discloses or suggests Applicants' claimed invention because, for example, neither applied reference (1) predetermines nutrient values of an end product; or (2) predicts end product UIP level according to temperature achieved during cooking and/or drying. Accordingly, even if one of ordinary skill in the art were properly motivated to combine these two references in some way (which they are not, at least for reasons discussed above), the resultant modification of Hietritter would not result in, or render obvious, the claimed invention.

Applicants also respectfully submit that there is a song in the musical, The Sound of Music, which appears to apply to this situation. The song contains a verse which says that "nothing comes from nothing, nothing ever could . . ." Applicants respectfully submit that

because there is nothing in either reference that discloses (1) predetermining nutrient values of an end product; or (2) predicting end product UIP level according to temperature achieved during cooking and/or drying, there is no basis in these references, either alone or in combination, for disclosing, suggesting, or otherwise rendering obvious, the claimed invention.

X. On page 8 of the Office Action, it is stated that Heitritter teaches of a base composition with soybean and/or corn meal, and just because Heitritter's preferred starting material is not soybean or cornmeal does not teach away from using soybean or cornmeal as a base composition.

In response to this, Applicants respectfully submit that the only disclosure by Heitritter regarding corn or corn byproducts appears to be in Table V, which concerns a feeding experiment using treated soybean meal. The experimental design employed a negative control (untreated soybean meal), and a positive control (corn gluten meal as a protein source). Experimental treatment #1 used treated soybean meal, and experimental treatment #2 used treated soybean meal plus methionine. The corn gluten meal was only used as a positive control with which to compare the soybean and is not part of the Heitritter invention in the sense that corn or corn by-products are simply not used as starting or end products.

Accordingly, reconsideration and withdrawal of this rejection are respectfully requested.

### Conclusion

All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding rejections and that they be withdrawn. It is believed that a full and complete response

has been made to the outstanding Office Action, and as such, the present application is in condition for allowance.

If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone Robert J. Webster, Registration No. 46,472, at (703) 205-8076, in the Washington, D.C. area.

Prompt and favorable consideration of this Amendment is respectfully requested.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Dated: August 3, 2007

Respectfully submitted,

By: 

Robert J. Webster

Registration No.: 46,472

BIRCH, STEWART, KOLASCH & BIRCH, LLP

8110 Gatehouse Road, Suite 100 East

P.O. Box 747

Falls Church, Virginia 22040-0747

(703) 205-8000

Attorney for Applicant